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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,367

12/10/2007

Elan Ziv

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EXAMINER

NICHOLSON, KERI JESSICA

ART UNIT

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3772

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,367	Applicant(s) ZIV, ELAN	
	Examiner KERI J. NICHOLSON	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/4/2008, 8/6/2008, 2/6/2009, 6/14/2009, 9/17/2009, 10/5/2009, 1/13/2010, 5/10/2010, 5/23/2010, 6/2/2010.

DETAILED ACTION

This is the initial Office action for non-provisional application 10/593,367 filed December 10, 2007, which is a national stage entry of PCT/IL2005/000303 filed March 17, 2005 and claims priority to provisional applications 60/602,636 filed August 19, 2004, 60/555,979 filed March 25, 2004, 60/553,966 filed March 18, 2004, and 60/553,965 filed March 18, 2004. The information disclosure statements filed April 4, 2008, August 6, 2008, February 6, 2009, and June 14, 2009, were considered by the examiner on May 4, 2010. The information disclosure statements file September 17, 2009, October 5, 2009, January 13, 2010, May 10, 2010, May 23, 2010, and June 2, 2010 were considered by the examiner on June 10, 2010. In the response to the restriction requirement filed March 18, 2010, claims 1, 23, and 33 have been amended; claims 1-38 are currently pending.

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 12-22 in the reply filed on March 18, 2010 is acknowledged. In light of Applicant's amendments to the claims, the examiner hereby withdraws the restriction requirement set forth in the Office action mailed February 19, 2010 as all claims are now drawn to a single embodiment of the invention.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference characters 713 and 714 that are not mentioned in the description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any

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amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9, 29, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

5. Claims 9 and 29 recite the limitations "after said insertion" and "upon said insertion", respectively; however, there is insufficient antecedent basis for the phrase "said insertion" in the claims. For examination purposes, the above limitations have been interpreted as "after insertion" and "upon insertion", respectively.

6. Claim 36 recites the limitation "said removal"; however, there is insufficient antecedent basis for this limitation in the claim. For examination purposes, "said removal" has been interpreted as "said removing" as previously recited in claim 35, from which claim 36 depends.

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 12, 16-18, 21, 23, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by James (US Patent Pub. 2002/0083949).

9. Regarding claim 12, James discloses an apparatus (1/101) for treating pelvic organ prolapse comprising a main body (11/111) adapted to provide pelvic organ support when inserted into a vagina and an anchoring body (14/15/114) selectively affixed to the main body (Figs. 1-17; page 2, ¶ 32; pages 3-4, ¶ 45).

10. Regarding claims 16, 18, 23, and 27, James discloses that the apparatus is made from material having a modulus of elasticity (page 3, ¶ 36) such that it will be flexible and deformable at at least three point thereon in response to a force applied on it either while in the vagina or during removal.

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11. Regarding claims 17 and 28, the apparatus taught by James is disposable.
12. Regarding claim 21, James discloses that the anchoring body may be ovoid (Figs. 2 & 9; page 3, ¶ 37).
13. Regarding claim 29, James discloses that the apparatus does not directly compress a urethra upon insertion (page 3, ¶ 34 & 41).
14. Claims 12, 13, 16-18, 20, 22-24, 27, 28, 33, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaseki et al. (US Patent Pub. 2004/0084054).
15. Regarding claims 12 and 13, Kasecki discloses an apparatus (1/10) for treating pelvic organ prolapse comprising a main body (2/12) adapted to provide pelvic organ support when inserted into a vagina and an anchoring body (3/13) selectively affixed to the main body, wherein the main body is non-planar, extending along three axes (Figs. 1-11 & 44; page 2, ¶ 57-59; page 5, ¶ 84 & 86).
16. Regarding claims 16, 18, 23, and 27, Kasecki discloses that the apparatus, including the main body, is adapted to be flexible such that a force applied to it will cause some degree of deformation at at least three point thereon (Fig. 44; page 3, ¶ 66-67).
17. Regarding claims 17 and 28, the apparatus taught by Kasecki is disposable.
18. Regarding claims 20 and 22, Kasecki discloses that the anchoring body may be ring shaped or multi-sided (Figs. 1-11 & 39-43).
19. Regarding claim 24, Kasecki discloses that the main body is non-planar, extending along three axes (Fig. 44).
20. Regarding claims 33 and 35, Kasecki discloses a method of treating pelvic organ prolapse comprising the steps of inserting an apparatus (1/10) into a vagina for treating pelvic organ prolapse, positioning the apparatus within the vagina such that the apparatus exhibits a

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non-planar configuration, anchoring the apparatus within the vagina using an anchoring body (3/13), and removing the apparatus from the vagina (Figs. 1-11 & 44; pages 2-3, ¶ 57-60; page 5, ¶ 84 & 86).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claims 1, 2, and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over James as applied to claim 12 above, in view of Kaseki et al. (US Patent Pub. 2004/0084054, and in further view of Holt (US Patent 2,141,040).

23. Regarding claims 1, 2, and 11, James discloses that the main body is ring shaped and sized and shaped to apply appropriate pressure on lateral vaginal walls for treating pelvic organ prolapse, wherein the elastomeric characteristics of the ring shaped main body enables the main body to be flexible and foldable at at least three different points or along at least two axes, such that the main body elastically expands into a predefined shape upon placement within the vagina (page 3, ¶ 36 & 38). However, James fails to teach that the predefined shape is multi-planar and that the apparatus further comprises an applicator.

Kasecki discloses an apparatus (1/10) for treating pelvic organ prolapse comprising a main body (2/12) adapted to provide pelvic organ support when inserted into a vagina and an anchoring body (3/13) selectively affixed to the main body, wherein the main body is non-planar, extending along three axes (Figs. 1-11 & 44; page 2, ¶ 57-59; page 5, ¶ 84 & 86). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to

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modify the apparatus taught by James such that the main body is formed to have a multi-planar shape extending along three axes as taught by Kasecki for the purpose of more closely matching the natural curves a vagina to improve user comfort. However, the combination of James and Kasecki fails to teach that the apparatus further comprises an applicator.

Holt discloses an applicator (19+20) for enclosing a pessary for insertion into a vagina (Fig. 5; page 2, column 1, lines 5-15). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of James and Kasecki to include an applicator as taught by Holt since a novice user may feel more comfortable using an applicator to ensure the apparatus is properly placed within the vagina. Further, providing an applicator would improve sanitation since the user's hands do not need to come into contact with the interior portions of the vagina during insertion as evidenced by McKibben et al. (US Patent 4,356,817).

24. Regarding claim 7, James discloses that the apparatus is made from material having a modulus of elasticity (page 3, ¶ 36) such that it will be flexible in response to a force applied on it either while in the vagina or during removal.

25. Regarding claim 8, the apparatus taught by the combination of James / Kasecki / Holt is disposable.

26. Regarding claim 9, James discloses that the main body is adapted to not directly compress a urethra after insertion (page 3, ¶ 34 & 41).

27. Regarding claim 10, the combination of James / Kasecki / Holt discloses the invention substantially as claimed, as described above, and Kasecki further teaches that the main body may be provided with a varying degree of thickness, and therefore a varying degree of stiffness, along its length (page 3, ¶ 60). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of

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James / Kasecki / Holt to be provided with a varying degree of thickness / stiffness as further taught by Kasecki for the purpose of allowing easier deformation of the main body.

28. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over James as applied to claim 12 above, in view of Kasecki and Holt as applied to claim 1 above, and in further view of Davis (US Patent 4,307,716). The combination of James / Kasecki / Holt discloses the invention substantially as claimed as described above, but fails to teach that the apparatus further comprises a device displacer. Davis discloses a pessary comprises a string (26) to facilitate removal of the device (Figs. 1-2; column 2, lines 15-31). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of James / Kasecki / Holt to further include a removal string as taught by Davis for the purpose of making the apparatus easier for the user to remove.

29. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over James as applied to claim 12 above, in view of Kasecki and Holt as applied to claim 1 above, and in further view of Sheen (US Patent 2,580,133). The combination of James / Kasecki / Holt discloses the invention substantially as claimed, as described above, but fails to teach that the apparatus further comprises a soft external layer on at least a portion of the main body. Sheen discloses a pessary (P) comprising a ring shaped main body (13) having a soft external layer (10) made of sponge rubber (Figs. 2-3; column 1, line 52 – column 2, line 18) capable of enhancing comfort and preventing necrosis. At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of James / Kasecki / Holt to include a soft external sponge rubber layer as taught

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by Sheen in order to enable the apparatus to press firmly against the vaginal walls without causing discomfort.

30. Claims 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over James or Kasecki as applied to claims 12 and 23 above, in view of Davis (US Patent 4,307,716). James and Kasecki each discloses the invention substantially as claimed as described above, but fails to teach that the apparatus further comprises a device displacer. Davis discloses a pessary comprises a string (26) to facilitate removal of the device (Figs. 1-2; column 2, lines 15-31). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by either James or Kasecki to further include a removal string as taught by Davis for the purpose of making the apparatus easier for the user to remove.

31. Claims 15 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over James or Kasecki as applied to claims 12 and 23 above, in view of Sheen (US Patent 2,580,133). James and Kasecki each discloses the invention substantially as claimed, as described above, but fails to teach that the apparatus further comprises a soft external layer on at least a portion of the main body. Sheen discloses a pessary (P) comprising a main body (13) having a soft external layer (10) made of sponge rubber (Figs. 2-3; column 1, line 52 – column 2, line 18) capable of preventing necrosis. At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by either James or Kasecki to include a soft external sponge rubber layer as taught by Sheen in order to enable the apparatus to press firmly against the vaginal walls without causing discomfort.

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32. Claims 19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over James or Kasecki as applied to claims 12 and 23 above, in view of Hay (US Patent 2,146,574). James and Kasecki each discloses the invention substantially as claimed as described above, but fails to teach that the apparatus further comprises an applicator adapted for insertion of the apparatus. Hay discloses a pessary inserter to ensure the proper position of a pessary being used (page 1, column 2, line 52 – page 2, column 1, line 12). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by either James or Kasecki to include an applicator as taught by Hay since a novice user may feel more comfortable using an applicator to ensure the apparatus is properly placed within the vagina. Further, providing an applicator would improve sanitation since the user's hands do not need to come into contact with the interior portions of the vagina during insertion as evidenced by McKibben et al. (US Patent 4,356,817).

33. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over James as applied to claims 12 and 23 above, in view of Kasecki and Holt as applied to claim 1 above, and in further view of Enhorning (US Patent 5,224,494). The combination of James / Kasecki / Holt discloses the invention substantially as claimed, as described above, but fails to teach that the main body is provided with a hollow lumen and the apparatus further comprises a flexible tube attached to the main body. Enhorning discloses a pessary (10) comprising a hollow main body (12), a flexible tube (16) attached to and in fluid contact with the main body, a non-compressible fluid located within the lumen, and a blocking mechanism (30) slidably located on said tube thereby constraining the fluid within the lumen (Figs. 1-5; column 3, lines 44-57; column 4, lines 22-26 & 34-64). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of James / Kasecki /

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Holt such that the main body is hollow and includes a flexible tube fluidly connected thereto as taught by Enhorning for the purpose of providing a smaller device for insertion which may then be augmented to the appropriate size for treating the prolapsed organ.

34. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over James as applied to claims 12 and 23 above, in view of Kasecki and Holt as applied to claim 1 above, in further view of Enhorning as applied to claim 30 above, and in even further view of Tutrone, Jr. (US Patent 5,603,685). The combination of James / Kasecki / Holt / Enhorning discloses the invention substantially as claimed as described above, and Enhorning further teaches that the tube is connected to a means for inflating the pessary (column 3, lines 44-57). However, the combination of James / Kasecki / Holt / Enhorning fails to teach that the tube further comprises a reservoir space. Tutrone discloses that is well known to use a compressible fluid reservoir as a pump to inflate an inflatable pessary (column 8, lines 38-49). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of James / Kasecki / Holt / Enhorning such that the tube includes an reservoir space in order to inflate the main body as taught by Tutrone since it is an easy pump for a user to operate.

35. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasecki as applied to claim 33 above, in view of Hay (US Patent 2,146,574). Kasecki discloses the method substantially as claimed as described above, but fails to teach that the step of inserting the apparatus is facilitated by using an applicator. Hay discloses using a pessary inserter to ensure the proper position of a pessary being used (page 1, column 2, line 52 – page 2, column 1, line 12). At the time of the invention, it would have been obvious to one having ordinary skill in the

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art to modify the method taught by Kasecki such that the apparatus includes an applicator as taught by Hay since a novice user may feel more comfortable using an applicator to ensure the apparatus is properly placed within the vagina. Further, providing an applicator would improve sanitation since the user's hands do not need to come into contact with the interior portions of the vagina during insertion as evidenced by McKibben et al. (US Patent 4,356,817).

36. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasecki as applied to claims 33 and 35 above, in view of Davis (US Patent 4,307,716). Kasecki discloses the method substantially as claimed as described above, but fails to teach that the step of removing the apparatus is facilitated by a device displacer. Davis discloses a pessary comprises a string (26) to facilitate removal of the device (Figs. 1-2; column 2, lines 15-31). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the method taught by Kasecki such that the apparatus further includes a removal string as taught by Davis for the purpose of making the apparatus easier for the user to remove.

37. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasecki as applied to claim 33 above, in view of Zunker (US Patent 6,808,485). Kasecki discloses the method substantially as claimed, as described above, but fails to expressly teach the step of disposing the apparatus. Zunker discloses a method of treating pelvic organ prolapse using an incontinence insert (100) and disposing of it after use (column 2, line 65 – column 3, line 7; column 7, lines 23-26). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the method taught by Kasecki to include the step of disposing the apparatus as taught by Zunker in order to maintain a sanitary living space.

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38. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasecki as applied to claim 33 above, in view of James (US Patent Pub. 2002/0083949). Kasecki discloses the invention substantially as claimed, as described above, but fails to expressly teach that the step of positioning the apparatus does not apply direct pressure to a urethra. James discloses a method for treating pelvic organ prolapse by inserting an apparatus (1/101) for treating pelvic organ prolapse into a vagina and positioning the apparatus within the vagina such that the apparatus does not directly compress a urethra (Figs. 1-17; page 1, ¶ 8; page 2, ¶ 32; pages 3-4, ¶ 34, 41 & 45). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the method taught by Kasecki such that the apparatus does not apply direct pressure on the urethra as taught by James so as not cause discomfort to the user.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI J. NICHOLSON whose telephone number is 571-270-3821. The examiner can normally be reached on Monday - Thursday, 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

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PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJN

/Keri J. Nicholson/

Examiner, Art Unit 3772

6/16/2010

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772